

EXHIBIT 22

KIRKLAND & ELLIS LLP

AND AFFILIATED PARTNERSHIPS

Mark McLennan
To Call Writer Directly:
+1 212 909 3451
Mark.mclennan@kirkland.com

601 Lexington Avenue
New York, NY 10022
United States

+1 212 446 4800

www.kirkland.com

Facsimile:
+1 212 446 4900

September 19, 2023

By E-mail

**HIGHLY CONFIDENTIAL - OUTSIDE
COUNSEL EYES ONLY**

Anthony H. Sheh
Williams & Connolly LLP
680 Maine Avenue SW
Washington, DC 20024
asheh@wc.com

Re: *Arbutus Biopharma Corporation and Genevant Sciences GmbH v. Moderna, Inc. and ModernaTX, Inc.*, Case 1:22-cv-00252-MSG (D. Del.) – **Sample Requests**

Dear Tony,

Your September 6 letter is unresponsive to the questions raised in our August 24 letter, and any delay in moving this discussion forward in a meaningful manner is of Plaintiffs' own making. For example, we have repeatedly requested justification for your request for 50 samples per batch, but you have provided none. Instead, Plaintiffs take weeks to respond to Moderna's letters, which only repeat the same recycled position and demand for an immediate response. Moderna's investigations have also been hampered by Plaintiffs' continually shifting inquiries, including most recently asking Moderna to investigate the possibility of interrupting its continuous manufacturing process to collect mid-process samples.

As an initial matter, Plaintiffs' letter is unclear on what it is they are seeking and your understanding of what Moderna has offered to produce. [REDACTED]

[REDACTED] ¹ August 24, 2023 McLennan Letter. Specifically, Moderna offered to produce samples of drug product that were made with each part number of mRNA-LNP that was made, sold, or imported into the U.S.

¹ We note that Plaintiffs' complaint accuses the drug product of infringement.

KIRKLAND & ELLIS LLP

Anthony H. Sheh
September 19, 2023
Page 2

HIGHLY CONFIDENTIAL - OUTSIDE
COUNSEL EYES ONLY

With regard to availability of batches, Moderna has been working to ascertain this information but is continually frustrated by Plaintiffs' refusal to explain why it needs 50 samples of each batch from more than one thousand batches, or propose any more reasonable quantity. Plaintiffs have admitted to having their own analytical methods for determining lipid content and are well aware of the quantities necessary to run those methods. If Plaintiffs were aware of any method requiring 50 samples for a single batch, they would have identified it by now.

Based on the unprecedented amount that Plaintiffs have continued to seek and the absence of any justification, we can only interpret these RFPs as designed to burden and harass Moderna, and delay the litigation. Simply put, Plaintiffs' repeated requests for 50 drug product samples from *more than one thousand batches*, totaling more than *50,000 samples*, is absurd, and far more than Plaintiffs could ever hope to test with the current case schedule, let alone store in extreme temperatures. Plaintiffs have not even committed to actually testing each of the samples that Moderna produces. Plaintiffs' most recent demands for mRNA-LNP samples (100 mg of lipid for 10% of all batches) is still extreme—amounting to samples from at least 80 batches, totaling more than 8,000 doses.

[REDACTED]

If Plaintiffs were aware of a method that required such extreme amounts, Plaintiffs have had months to inform Moderna. Based on Plaintiffs silence, we can only assume that Plaintiffs have no good basis to request such extreme amounts.

To suggest that there is no burden on Moderna in producing such enormous quantities is baseless and ignores the extensive correspondence and conferrals in which we have detailed that burden: the costs of the materials and doses that are potentially diverted from sale, the extreme amount of time needed to physically inspect freezers and remove samples without impacting other samples, require necessary compliance documentation to justify their removal from regulatory retained samples, and require them for shipment in temperature-controlled conditions while maintaining adequate chain-of-custody documentation for a prescription drug product are all clearly extremely burdensome, time consuming, and expensive (which Plaintiffs have not even offered to pay for).

With regard to the number of samples that Plaintiffs seek, Plaintiffs' reliance on *Everlight Electronics Co., Ltd. v. Nichia Corp.* is misplaced, as Moderna is already agreeing to provide a comparable amount of discovery compared to what was ordered in *Everlight*. The 1,000 samples produced were the total number of samples across all accused products, not 1,000 samples of *each* accused product. 2013 WL 6713789, at *1-2 (D. Del. Dec. 20, 2013). There, the defendant had produced over 600 "part numbers" of the accused product, and was agreeing to produce a

KIRKLAND & ELLIS LLP

Anthony H. Sheh
September 19, 2023
Page 3

HIGHLY CONFIDENTIAL - OUTSIDE
COUNSEL EYES ONLY

limited number of samples of each part number, not samples from *every batch* of every part number as you demand here. *See* Civ. No. 4:12-cv-11758-GAD-MKM, ECF No. 173-3. For comparison, Plaintiffs’ demand for 50 samples of every batch equates to more than 50,000 samples—**50 times** the number of samples in *Everlight*. By contrast, Moderna has already identified a far smaller number of part numbers of accused product and components thereof and intends to make a reasonable production of samples of each. Finally, production of LED lights is clearly far less burdensome than production of an FDA-approved prescription drug product subject to compliance and regulatory holds, which requires complex storage at extreme temperatures. Tellingly, Plaintiffs have not come forward with any case suggesting that a defendant needs to produce 50 samples of more than 1,000 batches. Instead, Courts have denied motions to compel the production of “duplicative and irrelevant product samples” as “disproportionate to the needs of the case and unduly burdensome.” *Rembrandt Diagnostics, LP v. Innovacon, Inc.*, No. 3:16-cv-0698, ECF Nos. 127, 130, at 5-6 (S.D. Cal. Oct. 3, 2017). In *Rembrandt*, the requested product samples would have resulted in the production of 1,150 sample test cups, and despite Plaintiffs’ objections regarding defendants’ “unilaterally select[ing] representative samples,” the Court agreed that defendants’ production of representative samples was sufficient. *Id.*, at 5. The same is true here. Just like in *Rembrandt*, “due to the nature of the products, the requests at issue [a]re duplicative and burdensome.” *Id.*

In any event, based on its investigation to date, Moderna expects to have some amount of each commercial drug product batch manufactured in the U.S. in its possession, but notes that it must retain a certain amount for compliance with regulatory and/or statutory requirements. Asking Moderna to determine (for more than a thousand batches) from the quantity of retained samples available, how much has already been used for regulatory and/or statutory compliance purposes, and how much can be spared and/or is needed for future compliance purposes is an incredibly burdensome exercise. This is particularly true given Plaintiffs have refused to narrow the requests to a reasonable quantity or number of samples, let alone to a reasonable number of batches. Moreover, Moderna personnel in the various departments involved in these investigations are currently under immense pressure to rapidly distribute Moderna’s upcoming updated booster product in time for the fall season, which has limited the time available to assist with these requests. Moderna is willing to further investigate a reasonable and proportionate number of samples from a reasonable and proportionate number of batches if Plaintiffs are willing to narrow the request.

Please explain (1) your basis for the proposition that Plaintiffs are entitled to “select” batches, (2) what selection criteria Plaintiffs will use to “select” batches and how that would be consistent with the samples being treated as “representative,” (3) why Moderna’s proposal to produce samples from a recent batch is insufficient, and (4) why a sample of 10% of batches is required. Assuming Plaintiffs can answer these questions, we are willing to consider a proposed stipulation on representativeness and can be available to meet and confer.

KIRKLAND & ELLIS LLP

Anthony H. Sheh
September 19, 2023
Page 4

**HIGHLY CONFIDENTIAL - OUTSIDE
COUNSEL EYES ONLY**

Regarding the specific questions in Plaintiffs' email, such information is more properly sought through an interrogatory. But in the interests of cooperation, we will provide updates here:

- Moderna is working to collect a listing of all batches of mRNA-LNPs of Moderna's COVID-19 Vaccine that were made in the U.S. or imported into the U.S. We expect that the vast majority are already listed in the drug product spreadsheets that have already been produced.
- Moderna has produced specifications for relevant part numbers of mRNA-LNP and drug product. Moderna will update this information as needed throughout fact discovery as new part numbers are created and/or as we locate additional documents. We will look into your specific query regarding part number [REDACTED].

• [REDACTED]

- Moderna has produced an initial summary listing of lipid content testing. As discussed in separate correspondence, at Plaintiffs' request, Moderna continues to investigate collection of additional testing information in summary form, COAs, or through underlying raw data. We do not appreciate your demand that Moderna produce thousands of COAs within a matter of days after the parties have had productive discussions on the burden in manually collecting them one by one, with an understanding that Moderna would investigate alternative means of obtaining this information. We continue to expeditiously investigate these RFPs.

With regard to Plaintiffs' endless demands for other pieces of information—this time expiration dates—we are working to diligently collect this information and produce it in usable form. Although Moderna was working diligently to compile a comprehensive summary of batch information including expiry, disposition, etc., Plaintiffs insisted that we immediately produce a listing of batch numbers and then continues to demand immediate production of additional information piecemeal, which only increases the burden on Moderna and delays production.

Sincerely,

/s/ Mark McLennan

Mark McLennan